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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,238	06/04/2001	Jens Chr. Jensenius	09011-002003	6910

1444 7590 09/21/2005

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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/874,238	JENSENIUS ET AL.	
	Examiner	Art Unit	
	David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-23,26,37,41,43 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *19,23,26 and 45* is/are allowed.

6)☒ Claim(s) *18,20-22,37,41 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.00

Amendment of 6/29/05 has been entered. Claims 18-23,26,37,41,43 and 45 are pending. Claims 18-23,26,37,41,43 and 45 are under examination. The amendment has entered no new matter.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment has overcome previously stated issues as follows:

The objection(s) to the specification.

The objection(s) to the drawings.

The objection(s) to claim 44 under 37 CFR 1.75.

The rejection of claim(s) 44 under 35 USC 112, 2nd paragraph.

The rejection of claims 19-23,26,37,41 and 43-45 under 35 USC 112, 1st paragraph.

Upon reconsideration the following grounds of rejection are newly stated.

Claims 37,41 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The method of claim 37 does not enable the specific measurement of MASP-2 in a sample.

Since instant claim 18 does not require that the "antibody produced" by the method be one that specifically binds MASP-2, it is reasonable to consider that the claim would encompass any antiserum or monoclonal antibody that reacts or cross-reacts with MASP-1 (see prior art rejection infra) or with MASP-3 (see 2003/0186319 of record). Since the antibodies obtained by the method of claim 18 could have such cross-reactivity, the method of dependent claim 37 would fail to specifically measure MASP-2 expression.

It is to be noted that applicant's own specification (see 2002/0082209 of record) recognizes the problem of cross-reactivity. See [0103] teaching that antibodies are to be "tested for specific MASP-2 recognition". See [0104] teaching that "preferably the antibodies of the

invention are produced using fragments of the MASP-2 protein which lie outside highly conserved regions".

Claims 18 and 20-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over SUMITOMO (JP 07238100, Derwent Abstr. Attached).

SUMITOMO shows a mouse monoclonal antibody against a MASP which is deemed to be the same as MASP-1, which was the only MASP known as of the publication date. The rejection is based on the rational that instant claim 18 does not require that the "antibody produced" by the method be one that specifically binds MASP-2. It is therefore reasonable to consider that the claim would encompass any antiserum or monoclonal antibody that reacts or cross-reacts with MASP-1. Note that instant Fig. 2 shows several regions where MASP-1 and MASP-2 have 5-6 amino acid residues that are identical (5-6 residues constitute the size of a typical epitope bound by a monoclonal antibody). Thus when one follows the method of claim 18, one would reasonably expect that there would be a portion of the polyclonal antibody population, in an anti-MASP-2 antiserum, that is reactive/cross-reactive with MASP-1. The degree of antiserum cross-reactivity would vary among the antisera obtained from different individual animals; however, since claim 18 has set no limits that would rule out any degree of cross-reactivity with MASP-1, claim 18 is reasonably anticipated by an antiserum against MASP-1. Sumitomo immunizes mice with MASP-1 in order to obtain spleen cells producing antibodies against MASP-1. In such methods it is inherent/conventional to obtain serum samples from the immunized mice in order to confirm that an immune response has occurred, prior to obtaining the spleen cells. Any such serum sample from a mouse that has mounted an immune response against MASP-1 would constitute an antiserum to MASP-1 and thus anticipate.

With respect to monoclonal antibodies against MASP-2, as encompassed by instant claim 20, it is considered that, because MASP-1 and MASP-2 have the regions of identity/ high homology that are the size of an epitope, one would obtain monoclonal antibodies from fused spleen cells of mice immunized with MASP-1 that are also reactive/cross-reactive with MASP-2.

Regarding dependent claim(s) 21-22, note Sumitomo teaches that the monoclonal antibodies can be "used for elucidation of new complement activating path." While Sumitomo discloses no particular methods to accomplish this, it would be conventional to employ antibodies diluted in saline or PBS, which would constitute "pharmaceutical" diluents, irrespective of the intended use. Also it would be conventional to couple the antibodies to a label/marker --e.g. to conduct immunohistochemical staining, to measure serum/plasma concentrations of MASP-1, in order to elucidate the new complement activating path.

An IDS was filed 6/4/01. Since parent application 09/054,218 has been lost, the non-patent references are not available. Applicant should provide copies in the next response, to assure that these references will be considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 9/8/05 DAS

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644